

FEB 11 1997

K964803

**PREMARKET NOTIFICATION SUMMARY  
UNIVISION™ ECHOCARDIOLOGY SYSTEM  
Network Concepts, Inc.**

**SUBMITTER:**

Larry Sieb  
Division Manager, Cardiology,  
NetworkConcepts, Inc.  
2135 W. Greenview Drive  
Middleton, WI 53562

Tel: (608) 836-9334

Fax: (608) 831-8333

**DEVICE NAME:**

Classification: Class II

Common/Usual Name: Mini-Pacs (Picture Archiving and Communications System): Image Management System

Proprietary Name: UNIVISION™ Echocardiology System

**INTENDED USE:**

The UNIVISION™ Echocardiology System is a network system intended to use digital technology to acquire images from an echocardiography ultrasound system for viewing outside the exam room and long term storage and retrieval on digital media. The substantial equivalent device is TomTec Imaging Systems' TomTec P90 system, FDA 510K Number K950279.

**DEVICE DESCRIPTION:**

UNIVISION™ Echocardiology System is a real-time network system that provides review of echocardiograms either inside or outside the hospital environment. The exams are then archived on optical disc media. The UNIVISION™ Echocardiology System is comprised of three major subsystems: the Image Acquisition Unit (IAU); the Workstation; and the Archive Subsystem.

- The Image Acquisition Unit (IAU) interfaces to a variety of ultrasound systems and obtains the patient's information and image data during exams.

This information is stored locally on the IAU for access anywhere on the network.

- Workstations provide the review of either exams in progress or previous exams that may be stored anywhere on the network.
- The Archive Subsystem consists of a jukebox server and CD-R (Compact Disc - Recordable) for archive of the echocardiology exams.

All image transfers over the network and on-and-off the CD-R jukebox employ the MPEG-1 (ISO/IEC 11172) standard for video and audio compression at a 30:1 compression ratio.

The UNIVISION™ Echocardiology System is a network system that uses digital technology to acquire images from an echocardiography ultrasound system. The images may be viewed outside the exam room and are stored and retrieved on digital media. The substantially equivalent device is TomTec Imaging Systems', TomTec P90 system, FDA 510K Number K950279.

#### **COMPARISONS TO PREDICATE DEVICE:**

The substantially equivalent device is TomTec Imaging Systems', TomTec P90 system, FDA 510K Number K950279. The TomTec P90 has several options. The TomTec P90 configuration that is equivalent to the UNIVISION™ Echocardiology System includes the Stress Echo and Networking application packages. The TomTec 3D/4D Ultrasound and Contrast Densitometry applications are not functions implemented in the UNIVISION™ Echocardiology System.

The UNIVISION™ Echocardiology System is intended for use in ultrasound Echocardiology laboratories. It acquires echocardiograms from ultrasound imaging systems during the exam and transmits these over a network for review and archive onto CD-R optical discs.

To increase speed of transmission over the network and make storage economically viable, MPEG-1 compression is employed. The images show no significant difference between the original image from an ultrasound echocardiology system and that from the same image after MPEG-1 compression has been employed.

#### **CONCLUSION:**

The UNIVISION™ Echocardiology System is substantially equivalent to the legally marketed predicate device with regards to safety, effectiveness and intended use.